



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

5 1 7 4 '02 MAY 29 P2:38

MAY 24 2002

Mr. Paul M. Janson
Director of Operations
Infinity2, Inc.
14500 N. Northsight Boulevard
Suite 316
Scottsdale, Arizona 85260

Dear Mr. Janson:

This is in response to your letters of April 8, 2002 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Infinity2, Inc. is making the following claims, among others, for the product **InflamAway**:

"...and joint discomfort..."

"For relief, try Infinity2's InflamAway...to nutritionally support the body's healing processes."

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggests that it is intended to treat, prevent, cure, or mitigate diseases, namely inflammatory joint diseases. These claims, including the name of the product (i.e., InflamAway), do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

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Please contact us if we may be of further assistance.

Sincerely,

A handwritten signature in dark ink, appearing to read "John B. Foret". The signature is fluid and cursive, with the first name "John" and last name "Foret" clearly distinguishable.

John B. Foret

Director

Division of Compliance and Enforcement
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

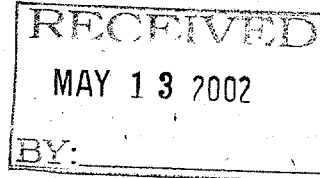
FDA, Los Angeles District Office, Office of Compliance, HFR-PA240



Premium
Enzyme Nutrition

8 copies

9/2/02



April 8, 2002

Corporate Headquarters

14500 N. Northsight Blvd.

Suite 316

Scottsdale, AZ 85260 USA

480-668-1800

480-668-1801 Fax

www.infinity2.com

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C. St. SW.
Washington DC 20204

To Whom It May Concern,

This letter serves as notification to the Food & Drug Administration under regulations 6.H.2 of statements used in the labeling of a dietary supplement. Infinity2, Inc. has begun the marketing of a dietary supplement that bears a statement listed under section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act.

Infinity2, Inc. is the distributor of a new product called "InflamAway". Infinity2 is located at 14500 N. Northsight Blvd., Suite 316., Scottsdale, AZ 85260.

The product label for "InflamAway" contains the following statement: "The muscle and joint discomfort associated with an active lifestyle is hard to ignore. For relief, try Infinity2's InflamAway - a proprietary blend of enzymes, powerful herbs and antioxidants to nutritionally support the body's healing processes. At the heart of Infinity2's all-natural InflamAway is CAeDS, an exclusive nutrient delivery system that guarantees maximum effectiveness."

The disclaimer that states, "These statements have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease." is included on the label. The disclaimer statement is listed with appropriate placement and typesize in harmony with the exemption to section 201(g)(1)(C) of the act that is provided by compliance with section 403(r)(6).

I certify that the information contained in this notice is complete and accurate, and that Infinity2 has substantiation that the statement is truthful and not misleading.

Respectfully,

Paul M. Janson
Director of Operations

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